

AMENDMENTS TO THE CLAIMS

In order to expedite prosecution, please amend the claims as follows, without prejudice to future prosecution, without disclaimer of any subject matter, and without acknowledgement or presumption that the amendments are in any way related to patentability.

1-14. (previously cancelled)

15. (previously amended) A diagnostic reagent for early detection of Lyme Disease, comprising a recombinant FlaA protein, wherein the protein comprises an amino acid sequence as shown in SEQ ID NO.:2.

16. (previously amended) The diagnostic reagent as in claim 15 wherein said recombinant FlaA protein comprises a fusion protein.

17. (previously amended) The diagnostic reagent as in claim 16 wherein said fusion protein is approximately a 38 kDa T7 gene 10 product.

18-20. (previously cancelled)

21. (previously amended) A diagnostic reagent for early detection of Lyme disease produced by a method comprising: providing freshly transformed host cells; constructing a DNA expression vector containing an expressible FlaA encoding DNA sequence; transforming a suitable host cell with said expression vector; plating out said transformed host cells; preparing large scale primary cell cultures from transformed host cells taken from a fresh transformant colony; and inducing FlaA protein expression from host cells in culture to produce a recombinant FlaA protein encoded by a nucleic acid sequence as shown in SEQ ID NO: 1.

amino acid sequence as shown in SEQ ID NO. 2

23. (previously amended) The recombinant FlaA protein of claim 21 comprising an amino acid sequence encoded by the nucleic acid sequence as shown in SEQ ID NO: 3.

24. (previously amended) A diagnostic reagent as in claim 21 wherein said recombinant FlaA protein is a fusion protein.

25. (previously amended) A diagnostic reagent as in claim 24 wherein said fusion protein is a 38 kDa T7 gene 10 product.

26. (previously amended) A diagnostic reagent as in claim 21 wherein said transformed host cell is an E. coli cell.

27. (previously cancelled)

28. (previously amended) A host cell containing the nucleic acid sequence of claim 21 or a complement thereof.

29. (previously amended) An expression vector comprising the nucleic acid sequence of claim 21 or a complement thereof.

30. (previously cancelled)

31. (new) A method for the diagnosis of Lyme Disease, the method comprising: contacting a sample to be tested with a recombinant FlaA protein, incubating for a sufficient time to allow formation of specific antibody-FlaA complexes, and detecting the antibody-FlaA complexes.

33. (new) The method of claim 32 wherein said fusion protein is an approximately a 38 kDa T7 gene 10 product.

34. (new) A method for producing FlaA protein, the method comprising: providing freshly transformed host cells; constructing a DNA expression vector containing an expressible FlaA encoding DNA sequence; transforming a suitable host cell with said expression vector; plating out said transformed host cells; preparing large scale primary cell cultures from transformed host cells taken from a fresh transformant colony; and inducing FlaA protein expression from host cells in culture to produce a recombinant FlaA protein encoded by a nucleic acid sequence as shown in SEQ ID NO: 1.

35. (new) The method of claim 34, wherein the FlaA protein comprises an amino acid sequence as shown in SEQ ID NO: 2.

36. (new) The method of claim 34, wherein the FlaA protein comprises an amino acid sequence encoded by the nucleic acid sequence as shown in SEQ ID NO: 3.

37. (new) The method of claim 34, wherein the FlaA protein is a fusion protein.

38. (new) The method of claim 37, wherein the fusion protein comprises an approximately 38 kDa T7 gene 10 product.

39. (new) The method of claim 34 wherein said transformed host cell is an E. coli cell.

40. (new) The method of claim 31, wherein the FlaA protein comprises an amino acid sequence as shown in SEQ ID NO:2.

42. (new) The method of claim 31, wherein the FlaA protein lacks a signal peptide.
43. (new) The method of claim 31, wherein the FlaA protein is immobilized on a solid support.
44. (new) The method of claim 31, wherein the FlaA protein further comprises a detectable label.
45. (new) The method of claim 44, wherein the label is selected from the group consisting of a chemiluminescent label, a radioactive label, and a colorimetric label.
46. (new) The method of claim 31, wherein the antibody-FlaA complex is detected by specific protein binding to the antibody specific for FlaA.
47. (new) The method of claim 31, wherein the antibody is of the IgM subclass.
48. (new) The method of claim 32, wherein the fusion partner of the FlaA fusion protein does not interfere with the antigenic epitopes of the FlaA protein.
49. (new) The method of claim 31, wherein the steps are performed manually.
50. (new) The method of claim 31, wherein the steps are automated.